REMARKS

Claims 11 – 32 are pending.

Applicants submit that the present application is now ready for examination on the merits. If, for any reason, the Examiner feels that an interview would be helpful to resolve any issues, he is respectfully requested to contact the undersigned attorney at (312) 321-4235.

Respectfully submitted,

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- SPECIFICATION.

Page 4, paragraph 2:

Such binding assays preferably are designed to specifically detect one or [few] more analyte molecules under investigation.

Page 5, paragraph 3:

Many assay set-ups are known from the art wherein at least one analyte specific component is coupled or linked to a hapten or a hapten-like molecule, e.g. biotinylated or digoxigenylated antibodies, etc. In a more generic manner the term haptenylated analyte specific component is used to indicate that a hapten or a hapten-like molecule is [covalent] covalently linked to an analyte specific component.

Page 6, paragraphs 3 and 4:

"Preferred derivatives and preferred analogues comprise the binding domain of the hapten or hapten-like molecule but may be modified as desired at those parts of the molecule not involved into the binding to the respective and appropriate analogue binding partner. Appropriate derivatives can be easily identified by their ability to improve an immunoassay as described in the present invention. [In case] Where biotin is used as the hapten-like molecule [a] preferred analogues of biotin are biocytin and biotin-methyl ester, the most preferred analogue of biotin is biocytin. It is preferred to use an analogue of a hapten or [a] of a hapten-like molecule in a method according to the present invention.

The free hapten or free hapten-like molecule may be added as a separate component to the reaction mixture or may be present in one of the reagent

combinations used to carry out the assay. It is preferred to carry out the assay in such ways that free hapten or free hapten-like molecule is added to or present in the reaction mixture before the haptenylated analyte specific component is present and the incubation step is performed. [The at] At least one incubation step therefore is characterized by the simultaneous presence of a haptenylated analyte specific component, a binding partner for the hapten or hapten-like molecule comprised therein, and the free hapten or hapten-like molecule. Incubation steps usually last from a few minutes up to a few hours.

Page 9, paragraph 5:

As discussed above, [the] skilled [artisan] artisans based on the state of the art knowledge and procedures may, [will have no problems] without requiring their own inventive efforts or undue burden [to him], [to] set up a binding assay employing a hapten or hapten-like binding pair. The following discussion is meant to further illustrate the invention but not to limit it to specific examples given.

Page 10, paragraph 5:

The final concentration of free hapten or hapten-like molecule will vary very much depending on the kind of binding assay used. Especially the concentration in relation to the haptenylated compound as used in the assay has to be determined carefully. Amounts or concentrations of free hapten or hapten-like molecule are preferred which lead to assay improvements in term of sensitivity and/or precision. In the case of homogeneous assays wherein the haptenylated compound is used [in] at a concentration of about 0.6 – 285 nM it is preferred to use 20 – 210 nM of free biotin in reagent R1 and a streptavidin load of 280 – 420 nM on the surface of the latex microparticles in reagent R2.

Page 20, before claim 1

What is claimed is:

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- CLAIMS.

What is claimed is:

11(new). A method for detecting or measuring an analyte in a sample by a specific binding assay comprising:

(a) providing a haptenylated analyte specific component comprising a first hapten or hapten-like molecule linked to an analyte specific component;

(b) providing a second hapten or hapten-like molecule which is not linked to the analyte specific component;

(c) providing an assay component comprising a binding partner which binds to both the first and the second hapten or hapten-like molecules, wherein neither the first hapten or hapten like molecule, the second hapten or hapten-like molecule, nor the binding partner interact with the analyte;

(d) combining the haptenylated analyte specific component, the sample and the assay component for an incubation step, wherein the second hapten or hapten-like molecule is present for at least part of the incubation step; and

(e) measuring a signal representative of the presence or concentration of the analyte.

12(new). The method of claim 11, wherein the analyte specific component is selected from a group consisting of the analyte, an analyte analogue, and a binding partner of the analyte.

13(new). The method of claim 11, wherein the second hapten or hapten like molecule is identical to, or an analogue of, the first hapten or hapten-like molecule.

14(new). The method of claim 13, wherein the first hapten or hapten-like molecule/ binding partner are selected from a group consisting of digoxin/anti-digoxin antibody, digoxigenin/anti-digoxigenin antibody, biotin/avidin, biotin/streptavidin, biocytin/avidin, and biocytin/streptavidin.

15(new). The method of claim 11, wherein the assay component comprises a particle linked to the binding partner.

16(new). The method of claim 15, wherein the specific binding assay is a homogeneous immunoassay.

17(new). The method of claims 11, wherein the second hapten or hapten-like molecule is present for the entire incubation step.

18(new). The method of claim 11 wherein the second hapten or hapten-like molecule is combined with the assay component prior to combining with the haptenylated analyte specific component.

19(new). A method to improve the sensitivity or precision of a specific binding assay for an analyte in a sample, wherein the specific binding assay components comprise a haptenylated analyte specific component comprising a first hapten or hapten-like molecule linked to an analyte specific component and an assay component comprising a binding partner which binds to the first hapten or hapten-like molecule, wherein neither the first hapten or hapten like molecule nor the binding partner interact with the analyte, the improvement comprising:

(a) providing a second hapten or hapten-like molecule which binds to the binding partner but does not interact with the analyte and is not linked to an analyte specific component; and

(b) combining the haptenylated analyte specific component, the assay component and the sample for an incubation step, wherein the second hapten or hapten-like molecule is present for at least part of the incubation step.

20(new). The method of claim 19, wherein the second hapten or hapten like molecule is identical to, or an analogue of, the first hapten or hapten-like molecule.

21(new). The method of claim 20, wherein the first hapten or hapten-like molecule/ binding partner are selected from a group consisting of digoxin/anti-digoxin antibody, digoxigenin/anti-digoxigenin antibody, biotin/avidin, biotin/streptavidin, biocytin/avidin, and biocytin/streptavidin.

22(new). The method of claim 19 wherein the analyte specific component is selected from a group consisting of the analyte, an analyte analogue, and a binding partner of the analyte.

23(new). The method of claim 19, wherein the assay component comprises a particle linked to the binding partner.

24(new). The method of claim 19, wherein the specific binding assay is a homogeneous immunoassay assay.

25(new). The method of claims 19, wherein the second hapten or hapten-like molecule is present for the entire incubation step.

26(new). The method of claim 19 wherein the second hapten or hapten-like molecule is combined with the assay component prior to combining with the haptenylated analyte specific component.

27(new). A kit for detecting or measuring an analyte in a sample comprising:

(a) a first reagent comprising a first hapten or hapten-like molecule linked to an analyte specific component;

(b) a second reagent comprising a second hapten or hapten-like molecule which is not linked to the analyte specific component; and

(c) a third reagent comprising a binding partner which binds to both the first and the second hapten or hapten-like molecules,

wherein neither the first hapten or hapten like molecule, the second hapten or hapten-like molecule, nor the binding partner interact with the analyte.

28(new). The kit of claim 27, wherein the second reagent is supplied combined with the first or third reagents.

29(new). The kit of claim 28, wherein the third reagent comprises a particle linked to the binding partner.

30(new). The kit of claim 28, wherein the analyte specific component comprises the analyte, an analyte analogue, or a binding partner of the analyte.

31(new). The kit of claim 28, wherein the second hapten or hapten like molecule is identical to, or an analogue of, the first hapten or hapten-like molecule.

32(new). The kit of claim 31, wherein the first hapten or hapten-like molecule/ binding partner are selected from a group consisting of digoxin/anti-digoxin antibody, digoxigenin/anti-digoxigenin antibody, biotin/avidin, biotin/streptavidin, biocytin/avidin, and biocytin/streptavidin.